# *Risk and What It Means to the Pharmaceutical Industry*

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## Abstract

In today's business climate, risk is key to creating and maintaining turnover within all industries. The term risk has long been researched on the perception of risk among people in both generic and specific disciplines, with no consensus on the definition of "risk" within the risk community.

This study aims to identify what risk means to the pharmaceutical industry, how it uses risk, and the effect of company culture on risk. There is no possible way to manage a company successfully without successfully managing its risks, with this study further investigating if utilising a risk framework would be beneficial to an organisation's management of risk.

The author has taken a mono method approach to this study, conducting seven semi-structured interviews, using qualitative data collection analysis. The approach allowed for an inductive method to be applied and deduce from the data findings to fill the research gaps identified in this study.

# Submission of Thesis and Dissertation

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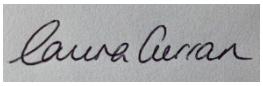
**Signature of research student:** 

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Finally, to the class of 2022 I will leave you with the wise words of Elle Woods, "It is with passion, courage of conviction, and strong sense of self that we take our next steps into the world. You must always have faith in people. And most importantly, you must always have faith in yourself." Congratulations guys, we did it!

# Contents

# Chapter 1: Introduction to the Thesis and Research Topic

## 1.1 Research Background

The term is risk has never been truly defined in any industry or the risk community with many attempts in specific disciplines to define over the years (Quintal, Lee, and Soutar, 2010; Larsen et al., 2011; Lepp and Gibson, 2003).

When discussing risk, the natural progression is to then consider risk assessments with many organisations such as the International Organization for Standardization and the Project Management Body of Knowledge advising on risk assessments. All of which can be applied to pharma, but it must be considered how these assessments work together within an organisation. Is there uniformity of what is risk, how it is dealt with, and the message as to the importance of risk conveyed thoroughly internally by pharmaceutical companies.

The Enterprise Risk Management framework allows companies to modernise their approach to risk, to identify, monitor and manage risks more effectively. By doing this, it gives companies the tools to meet their business goals and objectives.

Much of the research that has been carried out on risk and the ERM framework has not been within the pharmaceutical industry, and although there may be learnings from previous research that could be applied to the pharmaceutical industry, little has taken place within it.

## 1.2 Gaps in the Research

### 1.2.1Define risk in terms of the pharmaceutical industry

The term "risk" is a well discussed term with little consensus within the risk community as what risk is defined as. An apparent gap in the literature is not only the lack of agreement on what risk is but there is a distinct missing application to the pharmaceutical industry. If risk could be defined within the pharmaceutical industry, will it help the industry in how risk is dealt with.

### 1.2.2 Links between departments and types of risk assessments used

The literature provides detailed descriptions on qualitative and quantitative methods, but there is an incomplete knowledge of which methods are more appropriate and applicable to different departments within an organisation. This study will attempt to identify and understand the methods that different departments use when assessing risk.

### 1.2.3 Application of Enterprise Risk Management to the pharmaceutical industry

The pharmaceutical industry standard is to follow the International Council for Harmonisation of Technical Requirements for Pharmaceuticals in Human Use Q9, which focuses on quality and the risks associated with it. The literature suggests the ERM framework is to integrate ERM with corporate strategy, governance, and culture, but there is little evidence of pharmaceutical companies applying this framework internally. This study aims to find if there any benefit to applying the ERM framework to an organisation in the pharmaceutical industry.

### 1.2.4 Effect of company culture on risk management in pharma

The literature shows a strong correlation between company culture and risk management, but there is little application to studies being carried out on this link within the pharmaceutical industry. This study aims to identify if this link also exists within pharmaceutical organisations.

## 1.3 Research Objectives

**Objective 1:** *Define risk in the pharmaceutical industry.*
**Objective 2:** *Identify current risk assessments used.*
**Objective 3:** *Identify if there is a link between risk assessments used and business departments.*
**Objective 4:** *Identify if there is a link between risk management and company culture.*
**Objective 5:** *Identify biggest risks facing pharmaceutical companies.*

## 1.4 Research Question

> Overarching Research Question: *Would Irish pharmaceutical companies benefit from implementing the Enterprise Risk Management Framework across all business departments?*

The research questions originated from the author's interest in risk management when commercialising new pharmaceutical products. The author found that there was a lack of consistency across how risk management was used between business departments. This study's primary purpose is to evaluate how risk management is currently used and if pharmaceutical companies would benefit from implementing an overarching risk management framework to their business. The author examined the current literature to identify relevant areas that were worthy of investigation to develop findings on the potential benefit of the introduction of a framework.

Interview questions used for this study can be found in appendix 1.

## 1.5 Research Aim

Based on the literature gaps identified through the literature review in chapter 2, the aim of the study is to fill the gaps by identifying what risk meant within the pharmaceutical industry and if there is a benefit to companies introducing one single overarching framework for risk management such as Enterprise Risk Management framework.

Although there is literature on both risk management and the Enterprise Risk Management framework, there has been inadequate research carried out on these topics within the pharmaceutical industry.

## 1.6 Scope of Methodology

The literature review for this study provided distinct gaps in its application to the pharmaceutical industry, supporting the objectives of this study. The discussion in chapter 3 allowed the author to consider two types of general methods in their approach to the research: mono method or mixed method. The mixed-method approach uses both qualitative and quantitative methods (Saunders et al., 2019), with the author rejecting this due to the secondary data the author had found to support this study.

The author chose the mono-method, which is characterized by as one set of data, qualitative. Within the mono-method, there are several segments that can be used in a qualitative approach such as interviews or focus groups, to produce data findings. The author applied the mono-method through seven semi-structured interviews, to deduce data from the perspective of an employee within the pharmaceutical industry.

### 1.6.1 Primary Research Sample

This research was conducted using a qualitative, semi-structure interview approach, with seen individuals chosen due to their managerial positions in the pharmaceutical industry, which exposes them to risks in the industry and a deep knowledge of how to approach risk. The table below indicates business department, role, and length of service.

| Interviewee | Department | Role | Length of Service |
|---|---|---|---|
| **One** | NPI | Manager | 4 years |
| **Two** | NPI | Manager | 3 years |
| **Three** | NPI | Manager | 6 years |
| **Four** | Technical Support | Department Head | 3 years |
| **Five** | Business Development | Manager | 6 years |

| | | | |
|---|---|---|---|
| **Six** | Technical Quality | Department Head | 11 years |
| **Seven** | Analytical | Department Head | 7 years |

**Table 1:** Interviewee Information

### 1.7 Overview of Research Structure

***Chapter 1*** *– Background to the Research Topic*

The background of this study introduces a summary of the research topic risk management and its impact on the pharmaceutical industry. Also included in this chapter are the aims, objectives, scope of methodology and structure of this research.

***Chapter 2*** *– Literature Review*

The literature review contains both a review of current academic literature relevant to the research question, but also an overview of the pharmaceutical industry. The literature will be critically analysed to establish basis of this study, while the overview of the industry allows the reader to have a better understanding of the environment in which this study is set.

***Chapter 3*** *– Methodology*

This chapter discusses the philosophies, approaches, population sample, and data collection based on Saunders Research Onion. The author discusses the research objectives with the chosen methods and approach used to collect the primary data for this study.

***Chapter 4*** *– Findings and Discussion*

The chapter discusses the findings from the research, and critically analyses these findings using the literature from chapter 1.

**Chapter 5** *– Conclusions and Recommendations*

The conclusions and recommendations section are a summary and critical review of the research gaps found in the primary and secondary data, with a final summary on the final outcome of the research.

## Chapter 2: Literature Review

A literature review is a critical appraisal of a subject and while it gives understanding of the area, it is essential when planning research to establish any research findings in context. This chapter will be split into two sections to establish the scope of this study. Section one's focus

will be a literature review of risk management, art aspects of risk and risk frameworks typically used for risk management in all industries. Section two will be specific to the pharmaceutical industry, where an overview of risk management in the industry will be discussed, and challenges identified.

## 2.1 Definition of Risk

The term risk has long been researched on the perception of risk among people in both generic and specific disciplines. Perceived risk for financial (Quintal, Lee, and Soutar, 2010), food (Larsen et al., 2011) and health (Lepp and Gibson, 2003) are just a few of the areas that have attempted to define risk in their specific disciplines. Although risk management too is well established, with sources dating the origin of modern risk assessment between 1955-1964, and still there is no consensus on the definition of "risk" within the risk community.

There is consensus on how negatively risk management is viewed amongst the risk community, with the International Organisation of Standardization (ISO) (2018) defining risk as "the effect of uncertainty on objectives", with risk management known as "coordinated activities to direct and control an organization with regard to risk".

Hillson's (2002a) evaluation of what risk is lead to the conclusion that there are two options when defining risk. Firstly, risk can be looked upon as an umbrella term encompassing both the positive effects of risk which are an opportunity, and the negative effects of risk which are a threat. Secondly, taking "uncertainty" to apply to convey risk as either negative effect a threat, and positive effects an opportunity. With Hillson finding the risk community swaying more to accept the first when applying to risk management. Heldman (2005) also found the risk community to disregard positive outcomes and opportunities with majority categorising risk as negative consequences. Risks are nevertheless potential events, with an outcome that can be either positive or negative.

An opposing view of risk is to neither view the outcome of event as an opportunity or threat, but to take Hillson's second point as considering risk as "uncertainty". Chapman and Ward (1997) believed risk was an uncertain event that can cause an effect on performance. Aven (2010) argued that defining risk in an engineering setting was usually based on probabilities, with the conclusion this perspective is too narrow. He argued that only dealing with probabilities excluded uncertainty aspects. Jaafari (2001) defined uncertainty as an unknown

probability of occurrence of an event that derives from three principal sources, external factors, change of business strategies and ill-defined methods. Neither Chapman, Jaafari nor Aven focused on positive or negative but the "uncertainty" which can lead to variability in outcomes.

## 2.2 Risk Assessment

ISO 31000:2000 defines the term risk assessment as a tool that comprises of three steps: risk identification, risk analysis, and risk evaluation. Risk identification is when the organisation should identify the source of risks, the areas these risks impact, and potential outcomes. Risk analysis is the procedure of an upward insight of risk. Forsberg *et al*. (2005) emphasizes that completing a risk analysis can not be mistaken for a risk assessment or a risk management plan. Risk evaluation is used to support decision making, applying the risk analysis results to prioritize mitigation techniques to be implemented. Chapman (2001) discusses Privacy Risk Assessment Methodology (PRAM) which is sub-divided into sub-stages: qualitative analysis and quantitative analysis. Qualitative analysis focuses on identification and assessment, where Quantitative analysis focuses on evaluation. The PMBOK Guide (PMI, 2014) discusses the differentiation between qualitative and quantitative risk analysis agreeing that they have different focuses within risk assessments.

The Project Management Body of Knowledge (PMBOK) Guide defines qualitative analysis as risk prioritization. Thompson and Perry (1992) agree with PRAM in that qualitative risk analysis main two objectives are identification and assessment of risk, with Heldman (2005) supporting this by commenting that the purpose of qualitative risk analysis is to determine the consequences that the identified risks may have. Heldman considers qualitative risk analysis is the easiest and most widely used method for analysing risk. Restrepo (1995) found that decisions are more commonly made using qualitative assessments rather than quantitative, with Patterson (2002) finding the reason due to the ease and low cost in completing qualitative methods over quantitative. Although qualitative methods are a clear favourite among the risk community, they are found to contain more uncertainties and less accurate information.

The PMBOK guide defines quantitative risk analysis as the numerical analysis of the risk effect on a project. Heldman (2005) defines quantitative risk analysis further as the process of evaluating and quantifying risk exposure by assigning numeric values to the risk probabilities and the impact that these have. Thompson and Perry (1992) remark that quantitative analysis

includes complex analysis, with the process requiring estimates on probability and uncertainty. Cooper *et al*. (2005) acknowledged that quantitative analysis uses numerical values, rather than descriptive like qualitative. Chapman and Ward (1997) recognize the numerical value used to distinguish between targets, expectations, and commitments, and the pursuit of risk efficient ways to carry out projects.

The risk management process is applicable to all types of business activity across all departments within an organisation to aid decision making. This includes risk identification, analysis, evaluation, and mitigation. The most commonly used risk assessment techniques were collated and divided into qualitative and quantitative methods based on PRAM and PMBOK Guides previously mentioned and used for discussion in the research for this study.

## 2.3 Enterprise Risk Management (ERM) Framework applying to Pharmaceutical Industry

The pharmaceutical industry as a standard uses ICH Q9 mainly to focus the behaviours of industry and the regulatory authorities on the two principles of Quality Risk Management. "These are the evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient: and the level of effort, formality and documentation of the Quality Risk Management process should be commensurate with the level of risk" (ICH, 2022).

The ICH Q9 only applies to quality risks and neglects all other risks faced within pharmaceuticals, such as business risks, budget risks, and process risks to identify a few. There are other frameworks which should be considered for application in the pharmaceutical industry such as the Enterprise Risk Management framework.

The Committee of Sponsoring Organisations of the Treadway Commission (COSO) was established in the mid-1980s with a mission to "help organizations improve performance by developing thought leadership that enhances internal control, risk management, governance, and fraud deterrence." COSO created the enterprise risk management (ERM) model in 1992 which was a pyramid shaped model and only focused on evaluating existing controls. In 2013, the model was updated to the COSO cube, which focused mainly on the design and implementation of a risk management framework.

The 2013 COSO cube model was designed to illustrate the connection between the eight components: internal environment, objective setting, event identification, risk assessment, risk response, control activities, information & communication, and monitoring, with the four objectives: strategic, operations, reporting, and compliance. The components and objectives still apply to the 2017 update, but it is now in a helical shape and is known as "Enterprise Risk Management – Integrating with Strategy and Performance", with emphasis put on risk in processes and performance management.

Bowling and Rieger (2005) discuss how ERM has started to move from being purely theoretical to practical for financial institutions due to increasing regulatory scrutiny. They identified three success factors for ERM being the focus on strategy and business objectives, thinking broadly about the expansive range of risks an organisation faces, and recognising that ERM is a multi-year journey. These three challenges were accompanied by challenges; is the management strong enough to support and identify the strategy and business objectives, are there sufficient resources for ERM and as ERM is a multi-year journey, does the organisation have the stamina. Ultimately finding advantages of ERM significant as it supports the corporate governance process, controls the costs of risk management, and allows better understanding of an organisation's risks.

Andersen (2017) acknowledges how ERM has grown in popularity over the past two decades, reaffirming the change identified by Bowling and Rieger (2005), and recognises how it is now the stakeholders are driving the need for organisations to be "doing risk management right". Andersen (2017) identifies the same success factors and challenges as Bowling and Rieger (2005) but looks closer on an organisations internal auditor and how they can utilise the framework. He suggests internal auditors should become familiar with the fundamentals of the framework, focus less on internal controls and more on risk, managing risk, and reducing risk where recommended; they should not only evaluate internal controls but also managements implementation of risk responses, and finally, they should not focus blindly on always trying to reduce risk. Andersen's study found that 20% of respondent's organisations risk management process is a strategic tool which provides a competitive advantage, while 33% having a company which aligned their risk management and strategic planning. Andersen (2017) notes that not everyone will recognise the value in the COSO framework, giving internal auditors an invaluable opportunity.

Prewett and Terry (2018) build on Andersen's comments regarding internal auditors accepting internal control is a subset of broader ERM process, encompassed within the broader concept of governance. Criticism is found as it is not clear when ERM extends beyond a company's focus on internal control, meaning a lack of precision. The AAA Audit Committee raised concerns about the overlap of the ERM and Internal Control Framework, with many theoretical discussions about the relationship found in literature, but guidance on how to integrate the two is lacking. He concludes that it would be beneficial to receive more guidance on linking the system of internal controls with ERM but accepted the ERM framework is more to integrate ERM with corporate strategy, governance and culture, which intend to move firms to a leadership maturity level in ERM, resulting in higher firm value.

COSO continues to release updated guidance which reflects the changing global environments in which organisations operate. Cyber-attacks have been increasing over the last decade, with many companies falling victim. In 2017, Merck suffered an extraordinary blow from a Russian cyber-attack which used infected tax software application from an office based in Ukraine. The malware subsequently spread across Merck's organisation infecting an estimated 30,000 computers used in sales, manufacturing, and research divisions. It is projected that this caused $870m worth of damage but worse, it disrupted production of Gardasil 9, the HPV vaccine, directly impacting patients. In 2019, COSO published "Managing Cyber Risk in a Digital Age" to provide guidance for organisations on cyber risk management through the principle defined in the COSO ERM Framework.

The publication came as pharmaceutical companies had to quickly digitalise their processes and move swiftly to remote working and cloud-based solutions due to the Covid-19 pandemic. Unfortunately, Pfizer and AstraZenaca fell victim to cyber-attacks in 2020 in the race to release the first vaccine. Hackers edited accessed files before releasing, with the aim of undermining the public's trust in vaccines. SOPHOS solution brief released in 2021 reported 10% of pharmaceutical manufacturers are at high risk for ransomware with IBM (2021) reporting cost of data breach hitting record highs during the pandemic costing $4.24 million per incident on average. Cyber-attacks hit organizations profits and ultimately result on an impact to the patient.

Traditional risk assessment focuses on one area of an organisation, where Enterprise Risk Management encompasses the whole organisation.

## 2.4 Overview of risk management in Irish Pharmaceutical Industry

The ability of businesses to manage and react to quick changes, intense competition, consistent technological progressions, regulatory modifications, new customer agreements, and pressures of becoming more environmentally and socially responsible from legislation and policy has been the focus of many studies. These studies have concluded that to overcome these challenges, solutions will evolve using Certified Management Systems (CMSs). The most prevalent CSMs are from the International Organization for Standardization (ISO), which develop international standards and who's certification guarantees the entity meets global standards for business. These include ISO 9001 for Quality Management (QMS), ISO 14001 for Environmental Management (EMS), and ISO 45001 for Occupational Health and Safety Management Systems (OHSMS).

From the introduction of International Standardization in 1947, many industries have adhered to ISO management systems including construction, manufacturing, hospitality, health, and technology. Studies found that through the implementation of ISO Management Systems, there are a number of benefits as it is likely to improve the quality, lead time and processes alongside making the company more environmentally and socially responsible.

The pharmaceutical industry has also adopted many of the ISO Management Systems including standards to advise on the management of quality systems, medical devices, assets, bribery, security, and energy. Marinkovic *et al.* (2016) found that standardised management systems support companies to improve the business environment with a survey finding that there was high confidence in quality management systems. The benefits of these are seen in improved organisation performance, lower risk to employee safety, reduced energy costs, compliance with international regulations, high quality standards and improved data protection.

According to ISO, planning for risk is a form of quality management. The focus of risk management in the pharmaceutical industry has historically been concentrated around the quality of the product manufactured and reducing the risks involved in any pharmaceutical processes. Patient safety is at the core of all risk management practices in the pharmaceutical industry. Historically, finished goods would have undergone analytical testing in the late stages of production with failure of these tests resulting in huge financial implications.

Botet (2018) and Zameer (2017) both found that poor risk management had negative financial implications on business', with Zameer (2017) finding that poor decisions were made due to problems that were not considered and could have been mitigated. Now risk management has been established from the beginning of the supply chain due to the implementation of the Pharmaceutical Quality System (PQS) and Good Manufacturing Practice (GMP).

It is evident that these quality systems and the introduction of risk management have a significant effect on the success and performance of a company. Although the introduction of quality systems has had a positive impact on the business' finances, it is important to understand where else business risk management can be implemented and utilised to have the same impact and success that the introduction of quality management systems had.

Hillson and Murray Webster (2004) acknowledged that the management of risk through quality management systems can be categorised as hard skills and recognized the positive impact of these systems on the industry. However, in their study, they changed the focus from the impact of hard skills, practiced through the QMS, to assessing the softer skills of people's attitudes towards risk concluding that human factors, risk attitudes and emotions are all important considerations. A 2015 study carried out by Monteiro de Carvalho and Rabechini further focused on soft skills describing how the organisational context can affect risk, for example through organisation culture, as well as individual aspects like expectations, trust, and learnings.

Risk analysis in project management is a key practice to ensure that the project undertaken meets all stakeholder expectations and deadlines. By utilising risk management tools, risk can be identified and manged effectively to achieve project objectives, even leading to reduced rework costs (Lavanya and Malarvizhi, 2008). Risk management not only helps in avoiding crisis situations but also incorporates learnings from past mistakes.

Many older studies focused on characteristics of a project such as project size, allocated resources and project length being key influences on project success. This started to evolve through the nineties with studies conducted such as Clark and Fugimoto (1991) and Wheelwright and Clark (1992) considered how product complexity and customer interface complexity impact the risk perception.

Hillson and Murray-Webster (2004) study focuses on why risk attitude and emotional intelligence matters to risk management. They found that subconscious and unmanaged risk attitudes pose a significant threat to the ability of individuals and groups to achieve their objectives., with Wang *et al*., (2015) suggesting that company cultural norms and values shape employee's risk perception.

Organisations and their employees through industries such agriculture have been widely studied through many other papers such as Wauters *et al.* (2014) and Carvalho and Rabechini (2015) showing an understanding of risk attitudes and how important this is in business. Their findings concluded that soft skills in risk management had a larger impact on project success than first considered.

If risk management is weak in a company, then employees' attitudes and company culture should be evaluated as a starting point before implementing any procedural changes. If the attitude and culture are strong on the importance of risk management then the benefits will be reaped through project successes. Identification of a problem is key to begin improvements and what frameworks can be applied to strengthen this within an organisation.

## 2.5 Challenges in the Pharmaceutical Industry

The Pharmaceutical Industry is not exempt from the challenges that are facing the global economy with an economic slowdown, inflation, and geopolitical tensions to identify some. However, there are some challenges that are specific to the pharmaceutical industry, which are discussed by Flynn (2021) in an article published in the European Pharmaceutical review. In this, there are six major risks facing pharmaceutical manufacturing which will impact their recovery from the Covid-19 pandemic.

### 2.5.1 Reduced demand for prescription medicine

The lower demand for prescription medicine throughout the Covid-19 pandemic was due to reduced consumer confidence and decreased purchasing power. Reh *et al*., (2021) examined the hesitancy around the Covid-19 vaccine which identified trust as one of pharmaceutical manufacturers biggest issues. Although the Covid-19 vaccine is not a prescription medicine, it gave an opportunity to the issue to trust to be highlighted.

The pharmaceutical industry has historically been one of the least trusted industries worldwide, but a survey carried out by Accenture in 2021 found that 15% of US consumers say they trust pharma companies more than they did prior to the pandemic (Ahmed, 2021). Trust is crucial for companies to gain and maintain customers, as well as, attracting and retaining talent to keep making innovative healthcare breakthroughs, finding life-saving therapies.

Prior to the pandemic, the demand for prescription medicine had been increasing steadily due to aging populations, increased prevalence of chronic conditions and the development of new drug therapies. Economically there seems to be no change in sight for consumer purchasing power, but there is an opportunity for companies to make strategic choices to build trust.

### 2.5.2 Growing competition from generic pharmaceuticals

Many large pharmaceutical brands face loss of exclusivity across the US and Europe during the period from 2025-2030, with many brands facing generic or biosimilar competition for the first time. Merrill (2022) analysis forecasts that between them, the top 10 pharmaceutical manufacturers combined have an estimated 46% of their revenue at risk during this cycle.

The portfolio replenishment rate is falling for large pharmaceutical companies, with companies trying to react by increased spending in R&D, increasing from 14.4% to 17% over the last 10 years. (Merrill, 2022b). There are clear results from the extra spending on R&D, with pipeline drug growth in 2021 nearly twice of the 2020 rate. Innovation has been more successful for smaller indications, such as the Agios launch of Pyrukynd (2022) for patients with Pyruvate Kinase deficiency, with a clinically diagnosed prevalence between 3.2 and 8.5 per million in Western populations (Secrest *et al.,* 2020). There aren't the same big commercial winners hitting the market to make up for the potential losses for many of the large companies.

This will be significantly disruptive to the pharmaceutical market, which leaves a huge opening and opportunity for smaller manufacturers. With several more years until core LOE events, there is time for companies to utilise pipeline development and external business development to neutralize the effects of LOE events.

### 2.5.3 Pharmaceutical fraud

Pharmaceutical fraud account is one of the leading crimes in healthcare with a study written by Timofeyev *et al*. (2022) it costs billions annually in the US, with public companies more susceptible to the crime.

There are laws to help prevent healthcare fraud, such as the False Claims Act which encourages whistle-blowers to come forward about sales price fraud, clinical trial fraud, GMP fraud and industry bribes. There has also been the introduction of Serialization and Product Verification (IFPMA, 2013) which is a global anti-counterfeit strategy to support the fight against counterfeit medicines. Serialization secures the supply chain by assigning a unique code to the individual drug packaging of saleable prescription products.

Serialization is one of many steps being taken to prevent fraud reduce the number of fraudulent reimbursement claims.

### 2.5.4 Rising consumer expectations and difficulties managing brand health

Poor brand health is a major issue with pharma, and although it is an industry problem rather than individual companies. Articles written by Pearce and Kamal-Yanni (2018) for Oxfam, alongside many books and articles published by Ben Goldacre since 2012 discuss and promote the concept of drug companies undermining global health and misleading doctors, damaging the pharmaceutical industries brand.

Companies need to mitigate the risk of poor brand health by ensuring brand management is a high priority in their business strategy. They will need to manage the growing expectations of their customers and be prepared to respond to likely issues that are set to arise over the coming years, with a major issue facing all companies being supply chains.

### 2.5.5 Data breaches and cybersecurity threats

Cyberattacks are increasing annually targeting individuals, companies, and government agencies. Pharmaceutical companies such as Pfizer and Astra Zeneca are some of the examples of recent targets within the industry. Brooks (2021) reports that cybercrime is estimated to cost the world 10.5 trillion dollars annually by 2025, with nearly 80% of senior IT employees

believing their organisations lack sufficient protection against cyberattacks despite increased investments.

Consumer data and industries intellectual property are of high value to hackers so continued investment in cybersecurity will be required for the industry as these attacks become more serious and frequent.

### 2.5.6 Supply Chain disruptions

The global supply chain was left shaken by the Covid-19 pandemic as countries fought to control the spread by restricting travel and in-person activities (Guan *et al.,* 2020) and although there were hopes of a return to normality, the recent war in Ukraine has caused a further stumbling block on the road to recovery. The global supply chain is fragile, with the additional headache of Brexit for the Irish market, and pharmaceutical companies will have to strategize to mitigate the significant risks ahead.

The management of the six risks discussed will be key to pharmaceutical companies reaching their strategic business objectives.

# Chapter 3: Methodology

## 3.1 Introduction

The purpose of research is to apprise action and is a process embarked upon by individuals to investigate and increase their knowledge and understanding of a topic (Saunders, Lewis, Thornhill, 2015). According to Thomas (2017) research is identifying a problem to solve, some condition of incomplete knowledge or understanding, that the researcher attempts to shed some light on. Wilson (2014, p.2) advises that to answer a research question, the researcher is required to examine and analyse information that methodically and systemically increases knowledge on their proposed topic. Saunders, Lewis, Thornhill (2019, p.132) suggest that when designing and developing research, recognising differences, and philosophical incongruities is an inherent part of the research process.

## 3.2 Research Aims and Objectives

The focus of this study is to investigate the key drivers of risk management in the Irish Pharmaceutical sector. When considering what risk management means in the pharmaceutical industry, the answers are usually focused on quality of product. In a heavily regulated sector, product quality is key to survival of a pharmaceutical company, with business risks of equal importance. Risk management in business has been utilised mainly in the financial sector. The author wishes to investigate further the business risks affecting the pharmaceutical industry and if some lessons can be learnt from the practices being utilised in other sectors.

Aim: To investigate risk management in the pharmaceutical industry.

Objective 1: Define risk in the pharmaceutical industry.
Objective 2: Identify current risk assessments used.
Objective 3: Identify if there is a link between risk assessments used and business departments.
Objective 4: Identify if there is a link between risk management and company culture.
Objective 5: Identify biggest risks facing pharmaceutical companies.

## 3.3 Proposed Methodology and Design

The aim of this study is to investigate risk management in the pharmaceutical industry and evaluate if companies within the pharmaceutical industry would benefit from using an Enterprise Management Framework. Critical to this research is how risk is perceived by employees in the pharmaceutical industry, how they are currently using risk and is there an appetite for risk in their company culture. The aim of the author throughout the research process was to remain subjective and recognise variations within the data. In this chapter, the author discusses the methodology and subsequent methods that were considered for the research.

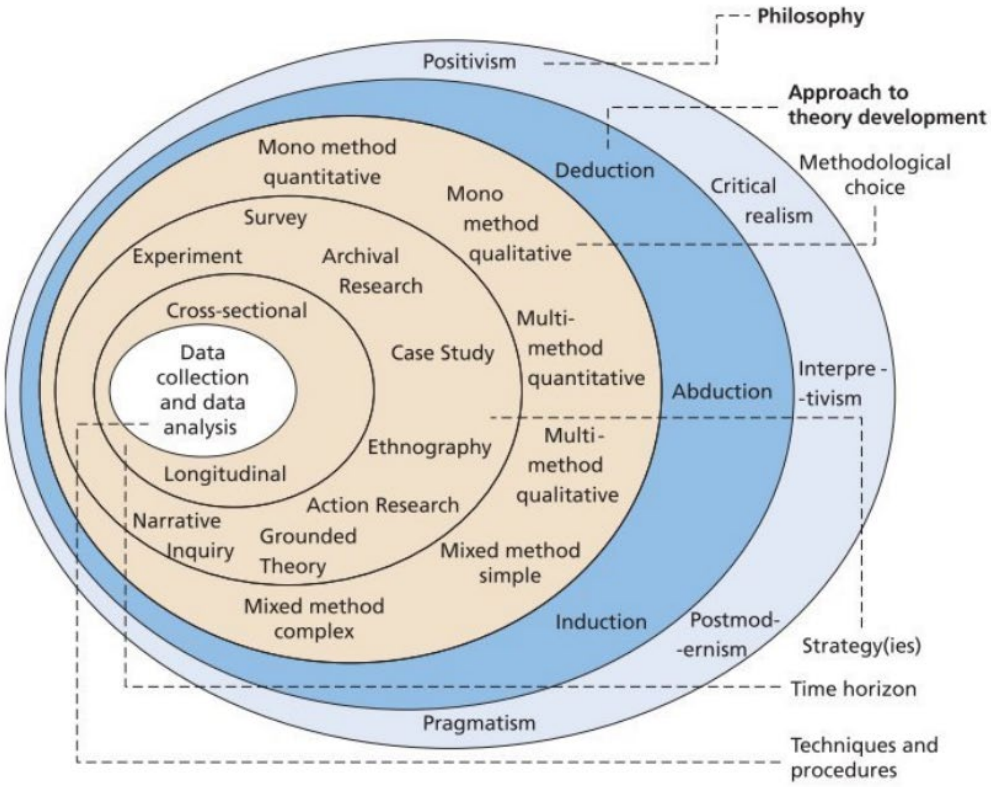


**Figure 1: Saunders Research Onion (Saunders *et al.*, 2019)**

The author has chosen the Saunders Onion as depicted in figure 1 as the guiding framework for the research methodology. Saunders et al., (2019) advise that many researchers plan their research in relation to a question that need to be answered, then identifies the data that is required to collect and the techniques to collect the data. The collection of the data is at the centre of the research 'onion', with the diagram illustrating the issues underlying the choice of data collection techniques and chosen analysis procedures.

Saunders, Lewis, and Thornhill (2007) created the research 'onion' in 2007 which contains an outer, inner, and central layer. The outer two layers are primarily concerned with philosophy and an approach to theory development. The inner layers examine the methodological choice, strategy, and time horizon. With the centre of the onion, as discussed previously, focusing on data collection and data analysis. Crucially, Saunders *et al*., (2007) suggest the researcher to unwrap the 'onion layer by layer, encouraging the researcher to address the outer layer before moving to the next.

The author employs the Saunders research 'onion' to discuss the philosophy, methods, strategy, design, data collection sample and analysis techniques, which are crucial to designing a reliable research methodology.

## 3.4 Research Philosophy

Saunders *et al*., (2019) defines research philosophy as a system of beliefs and assumptions about the development of knowledge. Research philosophies can vary due to the goals of the research, and on the best way that these goals may be achieved (Goddard and Melville, 2004). Dudovskiy (2018) acknowledges an individual's belief can influence the philosophical approach, with Wilson (2014) contending that a chosen philosophical approach should be determined by the researcher's ability to reject other applicable methodologies. The author intends to do this by developing knowledge in the role of risk management in Irish pharmaceutical companies. The aim of the author was to embark on this research with no bias or preconceived ideas, therefore following Saunders research 'onion' to choose the most appropriate philosophical approach. Saunders *et al*., (2019) explains that there are three different assumptions to distinguish research philosophies: ontology, epistemology, and axiology.

### 3.4.1 Ontology, Axiology, and Epistemology Approaches

| Assumption type | Questions | Continua with two sets of extremes | | |
|---|---|---|---|---|
| | | **Objectivism** | ⇔ | **Subjectivism** |
| **Ontology** | • What is the nature of reality? | Real | ⇔ | Nominal/decided by convention |
| | • What is the world like? | External | ⇔ | Socially constructed |
| | • For example: | One true reality (universalism) | ⇔ | Multiple realities (relativism) |
| | – What are organisations like? | Granular (things) | ⇔ | Flowing (processes) |
| | – What is it like being in organisations? | Order | ⇔ | Chaos |
| | – What is it like being a manager or being managed? | | | |
| **Epistemology** | • How can we know what we know? | Adopt assumptions of the natural scientist | ⇔ | Adopt the assumptions of the arts and humanities |
| | • What is considered acceptable knowledge? | Facts | ⇔ | Opinions |
| | • What constitutes good-quality data? | Numbers | ⇔ | Written, spoken and visual accounts |
| | | Observable phenomena | ⇔ | Attributed meanings |
| | • What kinds of contribution to knowledge can be made? | Law-like generalisations | ⇔ | Individuals and contexts, specifics |
| **Axiology** | • What is the role of values in research? Should we try to be morally-neutral when we do research, or should we let our values shape research? | Value-free | ⇔ | Value-bound |
| | • How should we deal with the values of research participants? | Detachment | ⇔ | Integral and reflexive |

**Figure 2: Philosophical Approaches (Saunders *et al.*, 2019)**

Ontology refers to assumptions about the nature of reality, with ontological assumptions shaping the researcher's perspective and investigation of their research subject, and in this studies case, the object being employees within the Irish Pharmaceutical Industry (Saunders *et al*., 2019). If the ontological approach was to be applied to this study it would allow the researcher to consider how certain they can be about the themes of their research, although critically it rejects the interviewees interpretations of reality (Katz, 2002). Axiology refers to the role of values and ethics. Silverman (3013) notes that it allows the researcher to analyse the impact that people's opinions when collecting and analysing data. Heron (1996) argues that the researchers' values are the guiding reason for people's actions, and it is inevitable that these values will impact the research process, so it is critical that this is considered when analysing any findings.

Epistemology refers to assumptions about knowledge, and what the researcher can constitute as acceptable, valid, and legitimate knowledge, and how the researcher can communicate this

to others (Saunders *et al.,* 2019). Ontology is abstract by comparison, with epistemology allowing a range of data, facts, opinions, and narratives to all be considered legitimate. Based on this, the epistemological approach was deemed most appropriate by the author.

After the author's evaluation of the philosophical assumptions illustrated in the research 'onion', the conclusion was that the use of an epistemological approach allows the author to view the interviewee's responses as reliable and does not require explanation of the knowledge collected.

### 3.4.2 Interpretivist, Positivist, Pragmatism, Realism

Epistemology contains four philosophical positions: positivism, pragmatism and interpretivism (Saunders *et al.,* 2019). For this study positivist, pragmatism and realism were all rejected for varied reasons. If the study were to take a positivist's view, then data could have only been collected through empirical research resulting in the findings being only true, false or meaningless. Pragmatism is an approach which can be taken as an alternative to positivism or interpretivism when the researcher feels neither aligns with their approach. Finally, realism underpins a positivist approach.

Interpretivism highlights the impact that social and cultural factors can have on an individual. It is the most appropriate approach for this study as it is a critical application and analysis of individuals. As interpretivism is also of qualitative nature in contrast to positivism, it can be challenged and allow the researcher to extrapolate knowledge from their findings.

## 3.5 Research Approach

The research approach is the broad method which will be undertaken to carry out the study. Saunders *et al. (*2019) divide this into three categories: deductive, inductive, and abductive, but for this study the author will consider deductive and inductive, as abductive is a combination of both.

### 3.5.1 Deductive versus Inductive Research

Deductive and inductive are two terms found in the second layer of Saunders research 'onion'. The outer layer previously discussed allowed the author to develop the aim of the research and understand the limitations they might incur when carrying out their study.

According to Silverman (2013), the deductive approach develops the hypothesis upon a pre-existing theory from which the researcher can then formulate a research approach to test it. This approach is aligned with a positivist approach, allowing the formulation of hypotheses and quantitative research technique of statistical testing of results to an accepted level of probability (Snieder & Larner, 2009). Though Saunders *et al*. (2019), acknowledges a deductive approach can also be applied to a qualitative research technique, though the expectations would be formed by pre-existing research would be devised otherwise than through hypothesis testing. A deductive approach uses questionnaire format to create understanding of an observation which would then allow analysis through empirical data.

In contrast to a deductive approach, the inductive approach allows the researcher to create a theory rather than adopt a pre-existing theory. The emergence of the inductive approach was led by social science researchers in the twentieth century. An inductive approach is found to be less rigid, allowing for alternative explanations to be considered. Inductive research is more appropriate for a small study of interviewees in contrast to a large sample required for deductive research. This study will follow the inductive approach as it is commonly used for qualitative research, where interviews are carried out and the resulting data can be analysed to find patterns between interviewees.

### 3.5.2 Descriptive versus Exploratory

There are varying research designs discussed by Saunders *et al*. (2019): descriptive and exploratory, which are different when applied to each type of methodology.

Descriptive demonstrates how data is connected and depicts a situation, individual or occasion as it naturally transpires (Saunders *et al.,* 2019). Descriptive was rejected as a research design for this study as it is found to more quantitative in nature, meaning that it could be quite restrictive when applied to the semi-structured interviews proposed for this study. Exploratory was chosen due to its greater flexibility when developing interview questions, allowing the interviewee to answer more open-ended questions, giving the participants the opportunity to expand on their opinions and ideas. This also allows the researcher to extrapolate further data from the participants responses. Blumberg *et al.* (2011) advises that exploratory research allows the author to take an alternative direction in the study if required.

## 3.6 Research Strategy

There are two types of data collection methods: Quantitative and Qualitative. The research strategy of a qualitative or quantitative approach to a study is influenced by the authors research philosophy, which discussed previously is an epistemological approach.

### 3.6.1 Experimental, Action, Case Study

Experimental research involves testing existing theories, in a controlled environment and is deductive, aligning with a positivist approach. Action research is usually set in a practical space, such as this study, which is carried out in a workspace; the findings are then discussed with the participants and a cyclical approach is taken until a practical solution is generated for a problem. Due to this Experimental and Action research were rejected for this research.

Case Study approach has an objective to gain an in-depth understanding of the study, fitting with the researcher's inductive approach. Commonalities between sets of data can be drawn from the research and applied to pre-existing theories (Merriam, 1988).

### 3.6.2 Mono, mixed, multi

A mono method chooses either one data type – qualitative or quantitative, where mixed-methods would be utilising both qualitative and quantitative. Finally, a multi-method approach would use a wider range of approaches including multiple qualitative and quantitative data. Other examples of qualitative methods would be to use thematic analysis or content analysis.

After consideration of the limited research in risk management in the pharmaceutical industry, the researcher found that the mono method of qualitative was the most appropriate to use for this study. The authors approach of interpretivist and inductive approach, support the qualitative design for this study.

### 3.6.3 Cross sectional, longitudinal

The time horizon describes how many points in time that the researcher intends on collecting their data, with two options existing: cross-sectional and longitudinal time horizon. As the researcher intends on collecting data at one point in time, a cross-sectional time horizon was utilised.

Longitudinal time horizon was ruled out as the length of time the study was to be completed in was restrictive and also the researcher could not identify any benefits to carrying out a longitudinal study rather than cross-sectional.

***The qualitative approach taken is in the form of semi-structured interviews details below:***

1. *The data collection involved seven interviews.*
2. *Each participant took part in a 20-minute interview session.*
3. *Participants chosen for the study were employees in the pharmaceutical industry that deal with risk daily as part of their roles.*
4. *The purpose of the interviews is to gain insight into how they perceive risk across nine questions which are directly related to the research objective.*

## 3.7 Data Collection

Yin (2016) states that to support a research strategy, four essential design methods are to be considered: validity, trustworthiness, triangulation, and rival thinking. Validity and trustworthiness ensure the study has correctly translated the data, so the findings can be found to be accurate, and any bias identified, projecting authentic and reliable data. Triangulation gives the opportunity to reinforce the credibility of the findings, by linking this to literature and theories. Finally, rival thinking shows the authors research can be challenged by other researchers in the same field of study, allowing the authors research to be rejected.

To gain validity of the data collected, the author provided transcripts to each interviewee for their review and requested feedback on the accuracy of the records taken. No discrepancies were highlighted by any of the participants. Triangulation will be demonstrated during chapter four of this paper, where the discussion of the findings will be linked to prior literature identified to be relevant to this study found in the literature review.

### 3.7.1 Qualitative Primary Collection

This study used semi-structured interviews, conducted face-to-face, with audio recording, to allow participants to discuss their opinions on the research topic of risk management within the pharmaceutical industry. Saunders et al. (2019) explains how individual interviews are an effective way to give the researcher an insight into the participants beliefs, views, actions, and behaviours. As interviews can be designed to have two types of questions, a structured or qualitative approach, the author has decided to go with a mixed approach of semi-structured interview questions to allow the participants an opportunity to expand on their answers if they feel necessary, meaning the questions are not close ended, as may be found in a survey. The findings of the data collected through the semi-structured interviews are discussed in chapter four.

### 3.7.2 Analysis and Collection – Primary/Secondary Data

A literature review was conducted by the author of existing literature on risk and risk management across all industries. A review was also conducted of the pharmaceutical industry to understand the current environment it operates in, and the challenges that it faces. The process involved the review of books, journals, and other sources to allow the author to gain an understanding of the research topic. This analysis of the literature allowed the author to identify a major gap, which gave the author an opportunity to perform the research for this study.

The information gathered over a time of ten months with the main resources from the NCI library and online databases which gave access to journal articles and eBooks. The additional online sites used were from professional and trustworthy sources, which aided the fuller understanding of the research topic.

### 3.7.3 Population

The researcher interviewed seven individuals in managerial positions in the pharmaceutical industry through an audio recorded one-to-one in semi-structured interviews:

1. Rachel Beggs – Project Manager, New Product Introduction
2. Michelle Greaves – Project Manager, New Product Introduction
3. Donna Hamilton, PhD – Project Manager, New Product Introduction
4. Graeme Laid – Technical Support Group Leader
5. Rory Davidson – Business Development Manager
6. Wayne Robinson – Technical Quality Lead
7. Kris Wright – Global Analytical Team Leader

The seven interviewees were selected due to their management positions, and their influence in the risk management decision making processes within their organisations. They were also selected to provide a range of backgrounds, which gave a wider opinion of risk management across pharmaceutical business departments.

### 3.7.4 Analysing Qualitative Data

When conducting qualitative research, the researcher must prioritise the skill of active listening to fully understand interpret what the interview is communicating. Yin (2016) advises that if the researcher is to do this accurately then they must demonstrate five key tasks: Active

listening, having an inquisitive nature, sensitive of time management, differentiate between primary and secondary information, and finally dissever information from different sources.

According to Saunders et al. (2019) the researcher must not have a subjective bias to the results of the research so Yin (2016) recommends ensuring accuracy in collection of data, the data must be rechecked to guarantee a thorough and complete analysis.

## 3.8 Ethical Issues

Blumberg *et al*., (2011) recognize that ethical issues may occur in every investigation and all parties involved in the process should exhibit ethical behaviour, as expected in other aspects of business. Ghauri and Grohaug (2005) address research ethics referring these as the moral principles and values that influence how researchers perform their research, without causing harm of any kind to anybody.

In this investigation, the researcher adhered to an ethical code of conduct to avoid arising ethical issues throughout the process. All information and data obtained through semi-structured interviews were only used for the purpose of this thesis. The researcher-maintained integrity and objectivity, respecting the privacy of all interviewees. The participant's participation was voluntary and were ensured the right to withdraw from the investigation process at any stage.

An Ethical Review Application Form was submitted to National College of Ireland by the author of this study, to ensure compliance in treatment of participants in an ethical manner.

## 3.9 Limitations to Research

The research conducted a small sample size of seven interviews within the same company, therefore the author concedes that the results may not be as conclusive, as bias and subjectivity can be expected. Upon reflection, the author would have conducted a larger and more diverse sample size to include employees from several pharmaceutical companies and also expand the departments included to give more insight into the investigation, reducing the bias and subjectivity within this study.

# Chapter 4: Research Findings and Discussion

## 4.0 Introduction

This chapter will present the findings from the seven, semi-structured, interviews recorded during June 2022. The data collection and analysis follow the methodology described and discussed in chapter three, which aims to present parallels between the data collected in this study and current literature from chapter two. This research has explored the gaps identified within the constructs of the study's research design.

There was a total of nine questions (see appendix 1) in which the discussion below will reference responses collected from the participants of this study.

### Research Objective 1: Define risk in the pharmaceutical industry.

The literature review suggests that risk can be considered in two ways: firstly, risk can be looked upon as an umbrella term encompassing both the positive effects of risk which are an opportunity, and the negative effects of risk which are a threat. Secondly, taking "uncertainty" to convey risk as either a negative effect (threat), or positive effects (opportunity) (Hillson, 2002).

Although Uncertainty featured heavily within the literature, it was not mentioned by any of the respondents in this study. The participants featured more heavily on negative effects of risks, essentially threats.

*'An action/ process that can cause issues or problems. It has an element of danger.*' (IV3)

*'The potential for issues / obstacles to present themselves during the course of a project*.' (IV5)

*'An action or process that needs controlled as its failure could have direct impact to the product or the patient'* (IV6)

This finding corresponds with the finding of Heldman (2005) where their study found the majority of people who deal with risk, categorise it negatively.

*'Risk is the measure of how much harm can come from a hazard and how likely that hazard is to come to harm. Within the context of pharma, it mainly translates to working out what can go wrong from manufacturing processes that will potentially cause poor product quality.'* (IV7)

Although a firm definition was not established from the responses, several findings could be drawn. The first is that all participants included quality within their reply when discussing risk and what it personally meant to them in the workplace. A second finding was that how they perceived risk was specific to their job role. Thirdly, patient safety was a top priority as to why risk was important to them and ultimately why they consider risk in their jobs.

*'Risk is centred around patient safety. What risk does the work that we do impact on the end user of the drug product? Not only a focus on the critical aspects of our process but also the behaviours of our team to best protect the patient and the Business by establishing and maintaining a proactive risk prevention culture.*' (IV4)

Lastly, a link was found between the risks facing the pharmaceutical industry and the definition of risk with several participants referring to supply chain issues, financial issues, and lead times to the end user.

The lack of consensus amongst the respondents is similar to that of the risk community when it comes to defining risk. Consensus was found on two points: firstly, the perception of risk is negative and secondly, there was a clear recognition that risk management is vital for patient safety.

### Research Objective 2 and 3: Identify current risk assessments used, and if there is a link between risk assessments used and business departments.

The participants assessed the table provided which showed a list of qualitative and quantitative methods. They then identified and discussed the techniques that were frequently used within their department. The most popular qualitative techniques were reviews, brainstorming, root cause, risk matrix and FMEA, with the most quantitative technique was the Critical Path Method (CPM) and Expected Monetary Value Analysis e.g., Decision Tree Analysis.

This study found that the types of risk participants face vary based on their job roles in their respective departments. This translated into how each department used risk assessments, as the type of risk assessments used are consistent within each department but not across departments. Most departments utilised qualitative techniques with the exemption of the Business Development department which used a mixture of both qualitative and quantitative techniques, with a larger emphasis on the financial implications of winning or losing new business.

There is uniformity in why risk assessments are carried out and how they are used, it is clear that there is not an overarching goal set by the company to convey the importance of risk. The

advantages of adopting an Enterprise Risk Management framework would mean that the organisation would have better control of the costs of risk management, and also allow the organisation to give the employee's an opportunity to understand the organisation's risks, Bowling and Rieger (2005).

*'being able to apply an Enterprise Management Framework in this organisation would mean the review of effectiveness of the risk controls actions currently in place and allow the communication of risk across the wider business'* (IV7).

### Research Objective 4: Identify if there is a link between risk management and company culture.

As discussed in chapter two, there are many studies that believe there is a strong link between company culture and the appetite for risk within a company. All seven interviewees found that they felt a strong link between company culture and risk management, with all seven believing the company culture personally affects how they manage risk.

*"company culture can affect the appetite for risk as well as the response to it. We can be over cautious with some risks and cavalier with others, this primarily arises from poor assessment of risks with the introduction of too much human bias and opinions"* (IV7).

Chapter two discussed how soft skills can affect risk, for example through organisation culture, as well as individual aspects like expectations, trust, and learnings.

"*feeling comfortable to be able to share opinions whilst feeling like you are being listened to breeds improvement opportunity both top down and bottom up. Delivering on improvement ideas is also vital."* (IV4).

Studies also suggest that company cultural norms and values shape employee's risk perception, so education is key to understanding the company culture and expectations of an organisation:

*"the company is currently driving to educate employees of the importance of risk management and the benefits it can return to the business and staff"* (IV6).

This education was found to already to filtering through teams:

*"teams with a greater understanding of risk are making positive improvements towards effectively managing risk, however, some teams are still pulling in the opposite direction"* (IV2).

Although all seven interviewees agreed that they believe there is a strong link between company culture and risk management, their view may solely be based on the company that they are currently employed with as all seven interviewees are employees at the same organisation. Nevertheless, the results in this study can be interpreted to show that there are further findings that link company culture and risk management.

### Research Objective 5: Identify biggest risks facing pharmaceutical companies.

Chapter 2 discussed five of the biggest risks facing pharmaceutical companies at present: reduced demand for prescription medicine, growing competition from generic pharmaceuticals, pharmaceutical fraud, rising consumer expectations and difficulties managing brand health, data breaches and cybersecurity threats and supply chain disruptions.

Cyber Attacks and pharmaceutical fraud were highlighted as key risks from all respondents, as the introduction of serialisation in pharmaceuticals was the main reason why respondents were aware of fraudulent activities.

Rising consumer expectations was another key theme across all respondents but in varying forms: shortening time to market, reducing costs, offering a wider range of services, all without impacting quality of the product.

*"The increasing need to shorten the "speed to market" lead time, creates a significant risk to maintain the necessary quality standards required when supplying pharmaceutical products, as well as a greater financial risk as shortening lead times will inevitably lead to higher costs"* (IV5).

*"Ability to implement process improvements to shorten time to market, reduce costs and provide a cost-effective product / increase business competitiveness without having an impact on product quality."* (IV6).

Although product quality has been the main reason for risk management in pharma, as discussed introduction of Pharmaceutical Quality System (PQS) and Good Manufacturing Practice (GMP) were introduced for quality purposes, four interviewees still identified quality of material sourcing a risk that they face regularly in their job role.

*"For me, the biggest risks are supply issues with both of product to patients and raw materials to my company"* (IV7).

*"Supply chain pressures with increased costs, lead times for materials"* (IV4).

There seems to be an increase in supplier changes that may be linked to material supply after the global pandemic, and there is a need to ensure these are assessed appropriately to ensure no impact on current processes and maintenance of product quality.

Not mentioned by any respondents were the reduced demand for prescription medicine or growing competition from generic pharmaceuticals. This could be potentially due to the organisation that they are involved in, as the main drugs manufactured and packaged are for targeted diseases, with whom the prescription medicine would be funded through alternative routes and not solely by the patient, and that generic companies do not have the licences to supply.

One risk that was discussed by two interviewees were the dependency on the clients and products that their company works with and the business risk that this poses to revenue as they are reliant on the success of others. This risk is niche to the type of business that this organisation operates in so may not have the same importance across all pharmaceutical companies.

It is evident that the interviewees have industry wide knowledge of risks faced for all pharmaceutical companies and are aware of how these risks impact their jobs daily.

## Chapter 5: Conclusions and Recommendations

Risk means something different to everyone, it is what we are exposed to that determines how we assess risk. From the findings in this study, it can be concluded that although there is no definite consensus amongst participants on the definition of risk, there was unanimous agreement when it came to what it meant to them within their jobs in the pharmaceutical industry. This was ultimately one of patient safety.

The study found that risk management is used differently across business areas such as operations, business development, analytical testing, project management and quality as each are working to different standards. The separation between departments and how risk management is used is an issue because it does not allow for a cohesive approach to be taken. A strong link was found between the company culture and personal attitudes towards risk.

Patient safety is at the core of the pharmaceutical industry and to ensure this, risk must be prioritised. It seems that there will never be a consensus on the definition of risk but this study found that the definition of risk is insignificant to how the pharmaceutical industry can deal with it, the definition doesn't need to have consensus within the pharmaceutical industry or the

risk community. The importance of risk is to have consensus within an organisation on how risks are managed. Based on these findings, this study recommends in order to effectively manage risk across an organisation and create a unified risk aware company culture within an organisation, a risk framework such as the Enterprise Risk Management framework should be introduced to allow uniformity in any organisations approach to risk.

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# Appendix 1

i. What is your position and role in this division?

ii. How long have you been in the division/organisation?

1. How do you define risk?
2. What type of risks do you face in your projects?
3. From your point of view, what is risk assessment?
4. What risk assessment method(s) do you use?

| Qualitative Techniques | Quantitative Techniques |
|---|---|
| • Documentation Reviews<br>• (e.g., Lessons Learnt documentation)<br>• Brainstorming<br>• Root Cause Identification<br>• SWOT<br>• Delphi Technique<br>• Checklist analysis<br>• Assumption's analysis<br>• Risk Categorisation (e.g., Risk breakdown structure)<br>• Probability and Impact Matrix<br>• Heuristics (Rule of Thumb) | • Critical Path Method (CPM)<br>• Program, evaluation, review technique (PERT) analysis<br>• Expected monetary value analysis (e.g., Decision Tree Analysis)<br>• Sensitivity Analysis<br>• Variance Trend Analysis<br>• Numerical Approximations<br>• Monte Carlo Analysis |

**Table 1: Qualitative v Quantitative Techniques**

5. What type of projects are you managing in the company?
6. Do you feel like there is a strong link between company culture and risk management?
7. Do you think company culture impacts how you manage risk?
8. In your opinion, what are the biggest risks facing pharmaceutical companies?
9. Is there anything you would like to add?